

## **REMARKS**

### ***Status of the Claims***

The present Office Action addresses claims 1-6, 8-12, and 14-16, however claims 4, 6, 11, and 15 are withdrawn from consideration. Remaining claims 1-3, 5, 8-10, 12, 14, and 16 stand rejected. Applicant respectfully requests reconsideration of the pending rejections in view of the remarks herein.

### ***Amendments to the Claims***

Independent claim 1 is amended to delete some limitations previously added and to recite a spinal rod approximator system that includes a spinal implant having a rod-receiving member, and a spinal rod approximator. Claims 4 and 5 are amended to correspond to amended claim 1. Independent claim 12 is amended to recite that the opposed legs of the u-shaped distal portion extending outward from the implant-gripping portion are at the same axial height on the implant-gripping portion. Withdrawn claim 15 is amended to correct a typographical error. Support for these amendments can be found through the specification and in the drawings, such as in paragraphs [0025] and [0030] and FIGS. 1, 5A, and 5B of the published application. No new matter is added.

### ***Rejections Pursuant to 35 U.S.C. §112***

Claims 12, 14, and 16 are rejected pursuant to 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. In particular, the Examiner argues that “[t]he opposed legs of the U-shaped distal portion extending outward from the implant-gripping portion at the same axial height appears to be new matter.” Applicant respectfully disagrees.

At the outset, Applicant notes that independent claim 12 has been amended to recite that the opposed legs of the u-shaped distal portion extend outward from the implant-gripping portion at the same axial height *on the implant-gripping portion*. Paragraph [0030] of the published application clearly describes the u-shaped distal portion as preferably being “substantially planar to allow the opposed legs 22a, 22b to fit underneath the rod-receiving member of a spinal implant that is

implanted in bone.” Since the legs are planar, they necessarily extend outward at the same axial height. Moreover, FIG. 1 specifically illustrates that the opposed legs are at the same axial height on the implant gripping portion as only one of the opposed legs is visible from the side due to the legs being at the same axial height on the implant gripping portion, thereby providing clear support for this limitation in claim 12. Applicant further notes that 35 U.S.C. §112, first paragraph states that the specification “shall contain a written description of the invention . . . to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.” The specification of the present application clearly and precisely contains a written description of the invention that is more than sufficient to enable a person skilled in the art to make and use a spinal rod approximator where opposed legs of the u-shaped distal portion extend outward from the implant-gripping portion at the same axial height on the implant-gripping portion. Reconsideration and withdrawal of this rejection is therefore respectfully requested.

Claims 14 and 16 were apparently rejected only because of their dependencies on claim 12. Because claim 12 complies with the written description requirement as discussed above, claims 14 and 16 also comply with the written description requirement.

***Rejections Pursuant to 35 U.S.C. §102***

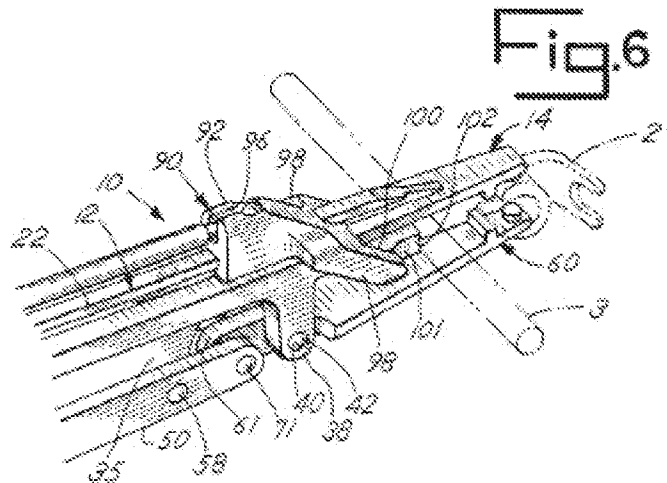
Claims 1-3, 5, 8-10, 12, 14, and 16 are rejected pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,020,519 (“Hayes”). Applicant respectfully disagrees.

***Claims 1-2, 5, and 8-10***

Independent claim 1 recites a spinal rod approximator system including a spinal implant having a rod-receiving member, and a spinal rod approximator. The spinal rod approximator includes an implant-gripping member having a u-shaped distal portion that extends in a direction substantially transverse to a longitudinal axis of a proximal portion of the implant-gripping member, a rod-engaging member slidably coupled to the implant-gripping member along the longitudinal axis of the proximal portion at a position proximal to the implant-gripping member, and a pusher member freely-rotatably coupled to at least one of the implant-gripping member and the rod-engaging member and threadably mated to the other one of the implant-gripping member and

the rod-engaging member such that rotation of at least a portion of the pusher member is effective to move at least one of the implant-gripping member and the rod-engaging member with respect to one another. The u-shaped distal portion includes opposed legs that extend under a distal end of the rod-receiving member of the spinal implant, and the rod-engaging member has a distal portion that extends transverse to a proximal portion.

Hayes does not teach or even suggest a u-shaped distal portion that includes opposed legs that extend under a distal end of a rod-receiving member of the spinal implant. Hayes discloses two parallel jaws 14, 60 each having two respective protrusions 44, 46, 62, 64 formed on a distal, inner surface thereof for engaging a rod-receiving head of an implant *therebetween*. In particular, two of the protrusions extend into bores formed in a sidewall of the implant, and the remaining two protrusions rest against a proximal surface of the head of the implant. As best seen in FIG. 6, reproduced at right, neither of the supposed u-shaped portions identified by the Examiner, i.e., one formed by the protrusions 44, 46 on jaw 14 and the other formed by the protrusions 62, 64 on jaw 60, extend under the distal end of an implant 2.



Accordingly, independent claim 1, as well as claims 2-3, 5, and 8-10 which depend therefrom, distinguish over Hayes and represent allowable subject matter.

Claims 12, 14, and 16

Independent claim 12 recites a spinal rod approximator including first and second components slidably coupled to one another and adapted for relative movement along a longitudinal sliding axis, and an actuator threadably coupled to one of the first and second components and effective to move at least one of the components with respect to the other component. The first component includes an implant-gripping portion offset from the sliding axis and a u-shaped distal portion having opposed legs that are adapted to be positioned under a distal end of a rod-receiving

member of a spinal implant, and the second component includes a rod-engaging portion offset from the sliding axis and being adapted to engage a spinal rod to move the spinal rod toward the rod-receiving member of the spinal implant being engaged by the implant-gripping portion. The opposed legs of the u-shaped distal portion extend outward from the implant-gripping portion at the same axial height on the implant-gripping portion.

Hayes does not teach or suggest opposed legs of a u-shaped distal portion extending outward from an implant-gripping portion at the same axial height on the implant-gripping portion. As clearly shown in FIG. 4 of Hayes, rotated and reproduced below, the legs 44, 46 that the Examiner relies on to form the claimed u-shaped portion are at different heights along the axis of the implant gripping member 60 as both the legs 44, 46 are visible from the side. Similarly, the legs 62, 64 are also at different axial heights on the implant gripping member 14. In contrast, by way of non-limiting example, opposed legs 22 are at the same axial height on the implant gripping member 12 (in Applicant's FIG. 1, reproduced below).

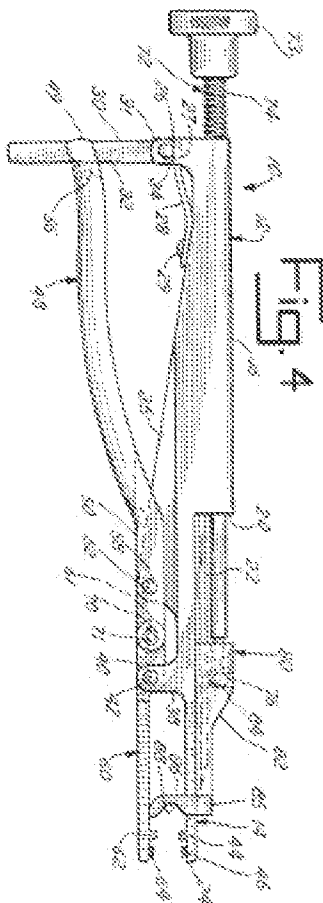
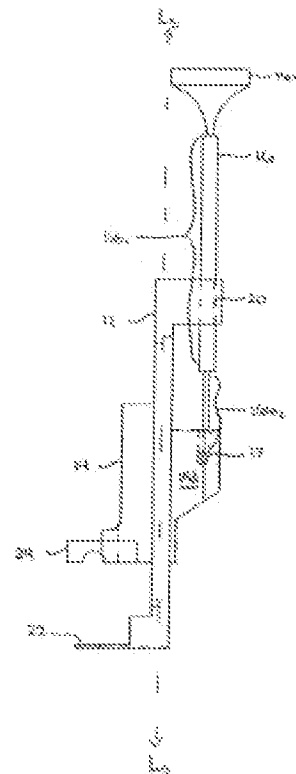


Fig. 1



Accordingly, independent claim 12, as well as claims 14 and 16 which depend therefrom, distinguish over Hayes and represent allowable subject matter.

***Conclusion***

Applicant submits that all claims are in condition for allowance, and allowance thereof is respectfully requested. Applicant's amendment of the claims does not constitute a concession that the claims are not allowable in their unamended form. The Examiner is encouraged to telephone the undersigned attorney for Applicant if such communication is deemed to expedite prosecution of this application.

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Respectfully submitted,

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